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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,045	01/03/2002	Jon Elliot Adler	P 280681 2001-019	3276

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,045

Applicant(s)

ADLER ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on n/a.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-234 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-234 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-119, 132-148, 150, 151, 177-222, 230, drawn to polynucleotides, classified in class 536, subclass 23.5.
 - II. Claims 120-130, 234, drawn to methods for assaying the activity of a GPCR and identifying activators of a GPCR, classified in class 435, subclass 7.21.
 - III. Claims 131, 149, drawn to methods of detecting a polynucleotide, classified in class 435, subclass 6.
 - IV. Claims 152-161, 166-170, 223-226, 231-233, drawn to polypeptides, classified in class 530, subclass 350.
 - V. Claims 162-164, 227-229, drawn to binding assays and methods of identifying binding partners, classified in class 436, subclass 501.
 - VI. Claim 165, drawn to antibodies, classified in class 530, subclass 388.22.
 - VII. Claims 171-176, drawn to methods of representing taste perception, classified in class 435, subclass 7.1

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I, IV and VI are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably

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distinct. Further, the protein of Group IV can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group IV, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group IV can be used in materially different methods other than to make the antibody of Group VI, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group VI can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II, III, V, and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group II requires an assay of GPCR activity, which is not required by any of the other groups. Group III requires hybridization and/or PCR assays, which are not required by any of the other groups. Group V requires competitive binding assays, which is not required by any of the other groups. Group VII requires mathematical modeling of taste perception, which is not required of any of the other groups.

The polynucleotides of Group I are related to the methods of Groups II, III, V, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

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another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups II, III, V, and VII because the polynucleotides of Group I can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups II, III, V, and VII are materially and functionally distinct from the others.

The polypeptides of Group IV are related to the methods of Groups II, V, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group IV are patentably distinct from each of the methods of Groups II, V, and VII because the polypeptides of Group IV can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups II, V, and VII are materially and functionally distinct from the others. Furthermore, the polypeptides of Group IV and the method of Group III are patentably distinct because one is not required for the use of the other.

The antibodies of Group VI are related to the methods of Groups II, V, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of

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Group VI are patentably distinct from each of the methods of Groups II, V, and VII because the antibodies of Group VI can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups II, V, and VII are materially and functionally distinct from the others. Furthermore, the antibodies of Group IV and the method of Group III are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Claims 1-132, 145-165, 170-234 are generic to a plurality of disclosed patentably distinct species of polynucleotides represented by a particular SEQ ID NO or polypeptides represented by a particular SEQ ID NO. Each SEQ ID NO represents a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO; and to search all species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, such species being appropriate to the Group chosen, e.g. if Group I is chosen then an appropriate species would be SEQ ID NO: 15, even though this requirement is traversed. Note that SEQ ID NO: 18 and 19 are consensus sequences and do not represent a particular polypeptide or polynucleotide sequence.

SEQ ID NO: 18 and 19 are generic to a plurality of disclosed patentably distinct species and thus do not, themselves, represent a species as defined in this Office action.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961.


Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER


August 22, 2004